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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,339	12/29/2005	Sean Frost	086671-0122	5052
23428 7590 04/02/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
SKELDING, ZACHARY S				
ART UNIT		PAPER NUMBER		
1644				
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04/02/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/528,339

Applicant(s)

FROST ET AL.

Examiner

ZACHARY SKELDING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-29-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's amendment to the claims filed December 29, 2005 is acknowledged.

Claims 9 and 11-13 have been amended.

Claims 1-16 are pending.

2. Restriction is required under 35 U.S.C. 121 and 372.
3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 11, drawn to a method of detecting osteolysis in a patient that has had a total hip replacement.

Group II, claim 12, drawn to a method of detecting osteolysis in a patient having primary or metastatic bone cancer.

Group III, claims 13 and 14, drawn to a method of detecting osteolysis in a patient having a metabolic bone disease such as Paget disease.

Group IV, claim(s) 15 and 16, drawn to a kit for detecting osteolysis comprising reagents for detecting CD4+CD25+ regulatory T cells and instructions for use.

5. Claims 1-10 link(s) the inventions of Group I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1-10. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting

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rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. The inventions listed as Groups I-IV above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions of Groups I-III do not share a special technical feature with respect to the patient population being analyzed by the claimed method in that each claim is drawn to a distinct patient population of unique etiology one to the other, and the invention of Group IV is a kit rather than a method of detecting osteolysis in a particular patient population. Furthermore, the special technical feature that is shared among the Groups of invention does not define a contribution over the prior art of Lewandrowski et al. (US 2002/0137082) in view of Seddon et al. (Immunol Today. 2000 Feb;21(2):95-9) and Heymann et al. (Drug Discov Today. 2005 Feb 15;10(4):242-7).

In particular, Lewandrowski teaches a method of detecting osteoporosis in a mammalian comprising: a) obtaining a sample of a bone related tissue or cells; and b) measuring the concentration of at least one marker selected from the group consisting of infectious agents, infectious agent produced factors, and heat shock proteins (HSPs) (see Lewandrowski, e.g., claim 1). Lewandrowski further teaches that osteoporosis induces the over-expression of heat shock proteins, which in turn are specifically recognized by regulatory T-cells leading to their activation (see Lewandrowski, e.g., pages 40, 1st paragraph to page 43, 1st paragraph).

Lewandrowski differs from the claimed invention in that it does not explicitly teach that CD4+CD25+ regulatory T cells should be measured as a proxy for osteoporosis.

However, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art that they could reasonably use detection of CD4+CD25+ regulatory T cells to detect osteoporosis given the teachings of Seddon, e.g., Figure 1 and Box 2, that regulatory T cells are CD4+CD25+ and antibodies for detecting these cell surface markers would have been well known to one of ordinary skill in the art.

Furthermore, it is evident that osteoporosis is considered by the art to be an osteolytic disease as shown by Heymann, see, in particular, page 242, right column.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

7. This application also contains claims directed to more than one species of the generic invention.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under **PCT Rule 13.1**.

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8. The species are as follows: “a method of detecting osteolysis by measuring CD4+CD25+ regulatory T cells in peripheral blood” AND “a method of detecting osteolysis by measuring CD4+CD25+ regulatory T cells in synovial fluid or tissue” AND “a method of detecting osteolysis by measuring CD4+CD25+ regulatory T cells in interface tissue between the failed component and the bone defect”. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.
9. Applicant is required, in reply to this action, to elect a single species, as applicable, which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by **37 CFR 1.141**. If claims are added after the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
March 26, 2008

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644